

(“Complaint”). This Answer is based upon Actavis’s knowledge as to their own activities and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the paragraphs in the Complaint.

AS TO THE ALLEGED NATURE OF THE ACTION

1. Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that Actavis filed Abbreviated New Drug Application (“ANDA”) No. 207079 with the United States Food and Drug Administration (“FDA”) seeking approval to market generic delayed-release esomeprazole magnesium products. Actavis denies the remaining allegations of this paragraph.

AS TO THE ALLEGED PARTIES

2. Actavis admits the allegations contained in Paragraph 2.
3. Actavis admits the allegations contained in Paragraph 3.
4. Actavis lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies them.
5. Actavis lacks knowledge or information sufficient to form a belief about the truth of the allegations of this paragraph and therefore denies them.
6. Actavis admits that Actavis Florida is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314, and admits that Actavis Florida is in the business of, among other things, developing, manufacturing and obtaining regulatory approval of generic pharmaceutical products for the United States market. Actavis denies the remaining allegations of this paragraph.
7. Actavis admits that Actavis Florida is a wholly-owned subsidiary of Andrx Corporation (a Delaware corporation, having its principal place of business at 4955 Orange

Drive, Davie, Florida 33314), which is a wholly-owned subsidiary of Actavis, Inc. (a Nevada corporation, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054). Actavis Florida denies the remaining allegations of this paragraph.

8. Actavis admits that Actavis Pharma is a Delaware corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admits that Actavis Pharma is in the business of, among other things, distributing and/or selling generic pharmaceutical products in the United States market, including products made by Actavis Florida or for which Actavis Florida is the applicant of an approved ANDA. Actavis denies the remaining allegations of this paragraph.

9. Actavis admits the allegations contained in Paragraph 9.

AT TO THE ALLEGED BACKGROUND

As To The Alleged NDA

10. Actavis lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations of this paragraph and therefore denies them.

As to The Alleged Patents-in-Suit

11. Actavis admits that United States Patent No. 5,714,504 (“the ’504 patent”) is entitled “Compositions,” was issued on February 3, 1998 and, according to the patent assignment database at the U.S. Patent and Trademark Office, was assigned to Astra Aktiebolag. Actavis denies the remaining allegations of this paragraph.

12. Actavis lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations of this paragraph and therefore denies them.

13. Actavis admits that United States Patent No. 6,369,085 (the “’085 patent”) is entitled “Form of S-Omeprazole,” was issued on April 9, 2002 and, according to the patent assignment database at the U.S. Patent and Trademark Office, was assigned to AstraZeneca AB. Actavis denies the remaining allegations of this paragraph.

14. Actavis lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations of this paragraph and therefore denies them.

15. Actavis admits that United States Patent No. 7,411,070 (the “’070 patent”) is entitled “Form of S-Omeprazole,” was issued on August 12, 2008 and, according to the patent assignment database at the U.S. Patent and Trademark Office, was assigned to AstraZeneca AB. Actavis denies the remaining allegations of this paragraph.

16. Actavis lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations of this paragraph and therefore denies them.

17. Actavis admits that United States Patent No. 8,466,175 (the “’175 patent”) is entitled “Form of S-Omeprazole,” was issued on June 18, 2013 and, according to the patent assignment database at the U.S. Patent and Trademark Office, was assigned to AstraZeneca AB. Actavis denies the remaining allegations of this paragraph.

18. Actavis lacks knowledge or information sufficient to form a belief about the truth of the remainder of the allegations of this paragraph and therefore denies them.

As to The Alleged ANDA

19. Actavis admits that it seeks the FDA’s approval for the proposed esomeprazole magnesium product that is the subject of ANDA No. 207079 (the “ANDA product”). Actavis denies the remaining allegations of this paragraph.

20. Actavis admits the allegations contained in Paragraph 20.

AS TO THE ALLEGED JURISDICTION AND VENUE

21. Paragraph 21 contains conclusions of law for which no response is required. To the extent that a response is required, Actavis admits this action cites the patent laws of the United States generally and this Court has subject matter jurisdiction.

22. Actavis admits the allegations contained in Paragraph 22

23. Actavis admits that Actavis Florida is in the business of, among other things, developing and manufacturing generic pharmaceutical products for the United States market. Actavis denies the remaining allegations of this paragraph.

24. Actavis admits that Actavis Pharma is in the business of, among other things, distributing and/or selling generic pharmaceutical products in the United States market, including products made by Actavis Florida. Actavis denies the remaining allegations of this paragraph.

25. Actavis denies the allegations made in paragraph 25.

26. Actavis denies the allegations made in paragraph 26.

27. Actavis admits that Actavis Laboratories FL, Inc. filed ANDA No. 207079 with the FDA. Actavis denies the remaining allegations of this paragraph.

28. Actavis admits the allegations made in paragraph 28.

29. Actavis Florida will not contest personal jurisdiction in this court for the purposes of this action only. Actavis Florida denies the remaining allegations of this paragraph.

30. Actavis will not contest personal jurisdiction over Actavis in this court for the purposes of this action only. Actavis denies the remaining allegations of this paragraph.

31. Paragraph 31 contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that Plaintiffs purport to base venue on 28

U.S.C. §§ 1391(c) and (d), and 1400(b). Actavis does not contest venue in this District for the limited purpose of this action.

AS TO THE ALLEGED FIRST CLAIM FOR RELIEF: '504 PATENT

32. Actavis restates and incorporates by reference their responses to the allegations of paragraphs 1-31 as though fully set forth herein.

33. Actavis admits that Actavis Laboratories FL, Inc. submitted ANDA No. 207079 to the FDA seeking approval to market generic delayed-release esomeprazole magnesium products. Actavis denies the remaining allegations of this paragraph.

34. Actavis admits that Actavis Laboratories FL, Inc. informed Plaintiffs that it had submitted a certification alleging that the '504 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA product. Actavis denies the remaining allegations of this paragraph.

35. Actavis denies the allegations contained in Paragraph 35.

36. Actavis denies the allegations contained in Paragraph 36.

37. Actavis denies the allegations contained in Paragraph 37.

38. Actavis denies the allegations contained in Paragraph 38.

39. Actavis denies the allegations contained in Paragraph 39.

40. Actavis denies the allegations contained in Paragraph 40.

AS TO THE ALLEGED SECOND COUNT FOR RELIEF: '085 PATENT

41. Actavis restates and incorporates by reference their responses to the allegations of paragraphs 1-31 as though fully set forth herein.

42. Actavis admits that Actavis Laboratories FL, Inc. submitted ANDA No. 207079 to the FDA seeking approval to market generic delayed-release esomeprazole magnesium products. Actavis denies the remaining allegations of this paragraph.

43. Actavis admits that Actavis Laboratories FL, Inc. informed Plaintiffs that it had submitted a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA product. Actavis denies the remaining allegations of this paragraph.

44. Actavis denies the allegations contained in Paragraph 44.

45. Actavis denies the allegations contained in Paragraph 45.

46. Actavis denies the allegations contained in Paragraph 46.

47. Actavis denies the allegations contained in Paragraph 47.

48. Actavis denies the allegations contained in Paragraph 48.

AS TO THE ALLEGED THIRD CLAIM FOR RELIEF: '070 PATENT

49. Actavis restates and incorporates by reference their responses to the allegations of paragraphs 1-31 as though fully set forth herein.

50. Actavis admits that Actavis Laboratories FL, Inc. submitted ANDA No. 207079 to the FDA seeking approval to market generic delayed-release esomeprazole magnesium products. Actavis denies the remaining allegations of this paragraph.

51. Actavis admits that Actavis Laboratories FL, Inc. informed Plaintiffs that it had submitted a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA product. Actavis denies the remaining allegations of this paragraph.

52. Actavis denies the allegations contained in Paragraph 52.

53. Actavis denies the allegations contained in Paragraph 53.

54. Actavis denies the allegations contained in Paragraph 54.

55. Actavis denies the allegations contained in Paragraph 55.

56. Actavis denies the allegations contained in Paragraph 56.

AS TO THE ALLEGED FOURTH CLAIM FOR RELIEF: '175 PATENT

57. Actavis restates and incorporates by reference their responses to the allegations of paragraphs 1-31 as though fully set forth herein.

58. Actavis admits that Actavis Laboratories FL, Inc. submitted ANDA No. 207079 to the FDA seeking approval to market generic delayed-release esomeprazole magnesium products. Actavis denies the remaining allegations of this paragraph.

59. Actavis admits that Actavis Laboratories FL, Inc. informed Plaintiffs that it had submitted a certification alleging that the '175 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA product. Actavis denies the remaining allegations of this paragraph.

60. Actavis denies the allegations contained in Paragraph 60.

61. Actavis denies the allegations contained in Paragraph 61.

62. Actavis denies the allegations contained in Paragraph 62.

63. Actavis denies the allegations contained in Paragraph 63.

AS TO THE PLAINTIFFS' PRAYER FOR RELIEF

(a) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (a).

(b) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (b).

(c) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (c).

(d) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (d).

- (e) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (e).
- (f) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (f).
- (g) Actavis denies that Plaintiffs are entitled to the relief requested in paragraph (g).

DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations found in the Complaint not otherwise admitted, Actavis avers and asserts the following defenses:

FIRST SEPARATE DEFENSE **(Non-Infringement)**

The manufacture, use, sale, offer for sale, or importation of the esomeprazole magnesium product that is the subject of ANDA No. 207079 (the “ANDA product”) has not, does not and would not infringe any valid and enforceable claim of the ’504, ’085, ’070 or ’175 patents either directly or indirectly, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE **(Invalidity)**

The claims of the ’504, ’085, ’070 or ’175 patents are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112.

THIRD SEPARATE DEFENSE **(Failure To State A Claim)**

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTH SEPARATE DEFENSE **(Other Defenses)**

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant Actavis Florida, Inc. (Actavis Florida), for its Counterclaims against Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca, Inc., (collectively “Plaintiffs”), alleges as follows:

PARTIES

1. Counterclaimant Actavis Florida is a Florida Corporation having a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

2. Counterclaim Defendant AstraZeneca AB purports to be a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden.

3. Counterclaim Defendant Aktiebolaget Hässle purports to be a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Counterclaim Defendant AstraZeneca LP purports to be a limited partnership organized under the laws of Delaware, having its principal place of business in Wilmington, Delaware.

5. Counterclaim Defendant Zeneca Inc. purports to be a Delaware corporation, having its principal place of business in Wilmington, Delaware.

JURISDICTION AND VENUE

6. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Plaintiffs because, on information and belief, Plaintiffs are actively and regularly engaged in business in the State of New Jersey and derive substantial revenues from things used or consumed in the State of New Jersey.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b). This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

BACKGROUND

9. AstraZeneca AB purports to be the owner of the '504, '085, '070, and '175 patents.

10. AstraZeneca LP purports to be the holder of New Drug Application ("NDA") No. 021153, directed to Nexium® (esomeprazole magnesium) Delayed Release Capsules.

11. The '504, '085, '070, and '175 patents are listed in the Orange Book with respect to the Nexium® drug product that is the subject of Plaintiffs' Complaint.

12. Actavis Florida filed ANDA No. 207079 with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) seeking FDA approval to market esomeprazole magnesium delayed-release capsules that are the subject of ANDA No. 207079 (the "ANDA product") in the United States. ANDA No. 207079 included a 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification ("Paragraph IV Certification") certifying that the proposed ANDA product will not infringe any valid and enforceable claim of the '504, '085, '070, and '175 patents.

13. In accordance with 21 U.S.C. § 355(j)(2)(B), Actavis Florida sent a letter to Plaintiffs on November 4, 2014 notifying Plaintiffs that it had filed ANDA No. 207079 with a

Paragraph IV Certification stating that the ANDA product will not infringe any valid and enforceable claims of the '504, '085, '070, and '175 patents.

14. On or about December 17, 2014, Plaintiffs filed a Complaint for patent infringement alleging that Actavis Florida's submission of ANDA No. 207079 infringes the '504, '085, '070, and '175 patents under 35 U.S.C. §271(e)(2)(A).

15. A definite and concrete, real and substantial, justiciable controversy exists between Plaintiffs and Actavis with respect to the validity and infringement of the '504, '085, '070, and '175 patents, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

COUNT I
(Declaratory Judgment of Invalidity of the '504 Patent)

16. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-15 as though fully set forth herein.

17. Upon information and belief, the claims of the '504 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT II
(Declaratory Judgment of Non-Infringement of the '504 Patent)

18. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-18 as though fully set forth herein.

19. Actavis Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '504 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell in the United States the ANDA product.

COUNT III
(Declaratory Judgment of Invalidity of the '085 Patent)

20. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-19 as though fully set forth herein.

21. Upon information and belief, the claims of the '085 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '085 Patent)

22. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-21 as though fully set forth herein.

23. Actavis Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '085 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell in the United States the ANDA product.

COUNT V
(Declaratory Judgment of Invalidity of the '070 Patent)

24. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-23 as though fully set forth herein.

25. Upon information and belief, the claims of the '070 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and 112.

COUNT VI

(Declaratory Judgment of Non-Infringement of the '070 Patent)

26. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-25 as though fully set forth herein.

27. Actavis Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '070 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell in the United States the ANDA product.

COUNT VII

(Declaratory Judgment of Invalidity of the '175 Patent)

28. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-27 as though fully set forth herein.

29. Upon information and belief, the claims of the '175 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and 103.

COUNT VIII

(Declaratory Judgment of Non-Infringement of the '175 Patent)

30. Actavis Florida restates and incorporates by reference the allegations set forth in paragraphs 1-29 as though fully set forth herein.

31. Actavis Florida will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '175 patent under 35 U.S.C. § 271 either by the manufacture, use, or sale in the United States of the ANDA product, or by meaningful preparation to manufacture, use, market, or sell in the United States the ANDA product.

PRAYER FOR RELIEF

WHEREFORE, Actavis Florida respectfully requests that the Court enter an order:

- A. Dismissing the Complaint with prejudice;
- B. Declaring that Actavis Florida's proposed esomeprazole magnesium product that is the subject of ANDA No. 207079 will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid and enforceable claim of the '504, '085, '070, and '175 patents under 35 U.S.C. § 271;
- C. Declaring that the claims of the '504, '085, '070, and '175 patents are invalid for failure to comply with one or more provisions of 35 U.S.C. §§ 102, 103 and/or 112;
- D. Declaring this case exceptional and awarding Actavis its reasonable attorneys' fees and costs under 35 U.S.C. § 285;
- E. Awarding Actavis Florida its costs; and
- F. Awarding Actavis Florida such other further relief as the Court deems just and equitable.

Dated: June 5, 2015

TRESSLER LLP

s/Robert J. Fettweis

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Inc. and Actavis Pharma, Inc.*

CERTIFICATION PURSUANT L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. MYLAN LABORATORIES LTD. and MYLAN, INC., C.A. No. 3:12-cv-01378-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA, C.A. No. 3:13-cv-01669-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC, C.A. No. 3:13-cv-04854-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA Inc., C.A. No. 3:13-cv-7298-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. KREMERS URBAN PHARMACEUTICALS, KREMERS URBAN DEVELOPMENT CO., and KREMERS URBAN LLC, C.A. No. 3:13-cv-7299-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA), C.A. No. 3:13-cv-4782-MLC-TJB (District of New Jersey)*
- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC. and ACTAVIS PHARMA, INC., 3:14-cv-07263-MLC-TJB (District of New Jersey, November 20, 2014)*

Dated: June 5, 2015

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